IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

VALIDUS PHARMACEUTICALS, INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. 08-36-GMS
	)	
ACTAVIS SOUTH ATLANTIC LLC, and ACTAVIS, INC.,	)	
	)	
	)	
Defendants.	)	

NOTICE OF SUBPOENA AD TESTIFICANDUM AND DUCES TECUM OF SHIRE LLC

PLEASE TAKE NOTICE that, pursuant to Rule 45 of the Federal Rules of Civil Procedure, Actavis South Atlantic LLC and Actavis, Inc., have served or will serve the attached subpoena *ad testificandum* and *duces tecum* on Shire LLC.

POTTER ANDERSON & CORROON LLP

By: */s/ David E. Moore*
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Dated: September 4, 2008
881117 / 32688

(Rev. 1/94) Subpoena in a Civil Case

Issued by the

UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF KENTUCKY

VALIDUS PHARMACEUTICALS INC.,

Plaintiff,

CIVIL ACTION NO. 1:08-CV-00036
(District of Delaware)

v.

ACTAVIS SOUTH ATLANTIC, LLC and
ACTAVIS INC.,
Defendant,

TO: **Shire LLC**, 9200 Brookfield Ct., Florence, KY 41042, through its registered agent, CSC-Lawyers Incorporating Service Company, 421 West Main St., Frankfort, KY 40601.

☐ YOU ARE COMMANDED to appear in the United States District Court at the place, date, and time specified below to testify in the above case.

PLACE OF TESTIMONY	COURTROOM DATE AND TIME

☒ YOU ARE COMMANDED to appear at the place, date, and time specified below to testify at the taking of a deposition in the above case.

PLACE OF DEPOSITION	DATE AND TIME
To be determined	To be determined

☒ YOU ARE COMMANDED to produce and permit inspection and copying of the following documents or objects at the place, date, and time specified below: See "Attachment A"

PLACE	DATE AND TIME
Vinson & Elkins The Terrace 7 2801 Via Fortuna Suite 100 Austin, TX 78746-7568	**October 3, 2008** **9:00 a.m.**

☐ YOU ARE COMMANDED to permit inspection of the following premises at the date and time specified below:

PREMISES	DATE

Any organization not a party to this suit that is subpoenaed for the taking of a deposition shall designate one or more officers, directors, or managing agents, or other persons who consent to testify on its behalf, and may set forth, for each person designated, the matters on which the person will testify. Federal Rules of Civil Procedure, 30(b)(6).

ISSUING OFFICER SIGNATURE AND TITLE (INDICATE IF ATTORNEY FOR PLAINTIFF OR DEFENDANT)	DATE
Erin Ator Thomson for Defendants	September 3, 2008
ISSUING OFFICER'S NAME, ADDRESS AND PHONE NUMBER Erin Ator Thomson, Vinson & Elkins L.L.P., 2801 Via Fortuna, Suite 100, Austin, Texas 78746; (512) 542-8762; fax (512) 236-3221	

(See Rule 45, Federal Rules of Civil Procedure, Parts C & D on Reverse)

AO88 (Rev. 1/94) Subpoena in a Civil Case

PROOF OF SERVICE

DATE PLACE

SERVED

SERVED ON (PRINT NAME) MANNER OF SERVICE

SERVED BY (PRINT NAME) TITLE

DECLARATION OF SERVER

I declare under penalty of perjury under the laws of the United States of America that the foregoing information contained in the Proof of Service is true and correct.

Executed on _____
DATE

SIGNATURE OF SERVER

ADDRESS OF SERVER

Rule 45, Federal Rules of Civil Procedure, Parts C & D:

(c) PROTECTION OF PERSONS SUBJECT TO SUBPOENAS.

(1) A party or an attorney responsible for the issuance and service of a subpoena shall take reasonable steps to avoid imposing undue burden or expense on a person subject to that subpoena. The court on behalf of which the subpoena was issued shall enforce this duty and impose upon the party or attorney in breach of this duty an appropriate sanction which may include, but is not limited to, lost earnings and reasonable attorney's fee.

(2) (A) A person commanded to produce and permit inspection and copying of designated books, papers, documents or tangible things, or inspection of premises need not appear in person at the place of production or inspection unless commanded to appear for deposition, hearing or trial.

(B) Subject to paragraph (d) (2) of this rule, a person commanded to produce and permit inspection and copying may, within 14 days after service of subpoena or before the time specified for compliance if such time is less than 14 days after service, serve upon the party or attorney designated in the subpoena written objection to inspection or copying of any or all of the designated materials or of the premises. If objection is made, the party serving the subpoena shall not be entitled to inspect and copy materials or inspect the premises except pursuant to an order of the court by which the subpoena was issued. If objection has been made, the party serving the subpoena may, upon notice to the person commanded to produce, move at any time for an order to compel the production. Such an order to comply production shall protect any person who is not a party or an officer of a party from significant expense resulting from the inspection and copying commanded.

(3) (A) On timely motion, the court by which a subpoena was issued shall quash or modify the subpoena if it

(i) fails to allow reasonable time for compliance;

(ii) requires a person who is not a party or an officer of a party to travel to a place more than 100 miles from the place where that person resides, is employed or regularly transacts business in person, except that, subject to the provisions of clause (c) (3) (B) (iii) of this rule, such a person may in order to attend trial be commanded to travel from any such place within the state in which the trial is held, or

(iii) requires disclosure of privileged or other protected matter and no exception or waiver applies, or

(iv) subjects a person to undue burden.

(B) If a subpoena

(i) requires disclosure of a trade secret or other confidential research, development, or commercial information, or

(ii) requires disclosure of an unretained expert's opinion or information not describing specific events or occurrences in dispute and resulting from the expert's study made not at the request of any party, or

(iii) requires a person who is not a party or an officer of a party to incur substantial expense to travel more than 100 miles to attend trial, the court may, to protect a person subject to or affected by the subpoena, quash or modify the subpoena, or, if the party in who behalf the subpoena is issued shows a substantial need for the testimony or material that cannot be otherwise met without undue hardship and assures that the person to whom the subpoena is addressed will be reasonably compensated, the court may order appearance or production only upon specified conditions.

(d) DUTIES IN RESPONDING TO SUBPOENA.

(1) A person responding to a subpoena to produce documents shall produce them as they are kept in the usual course of business or shall organize and label them to correspond with the categories in the demand.

(2) When information subject to a subpoena is withheld on a claim that it is privileged or subject to protection as trial preparation materials, the claim shall be made expressly and shall be supported by a description of the nature of the documents, communications, or things not produced that is sufficient to enable the demanding party to contest the claim.

EXHIBIT A

Pursuant to Rule 45 of the Federal Rules of Civil Procedure, Defendants Actavis South Atlantic, LLC and Actavis, Inc. ("Actavis") hereby serves this subpoena for documents and things.

Definitions

1. The terms "Shire," "you," and "your" means Shire PLC, Shire LLC, Shire US, Inc., Shire Laboratories Inc., and any parent, subsidiary, member and/or affiliated entity, past or present, of Validus, and any person or entity, past or present, acting on behalf of Shire, including, but not limited to, each of its present and former managers, officers, executives, directors, employees, attorneys, agents and/or representatives.

2. The term "Actavis" means defendants Actavis South Atlantic, LLC and Actavis, Inc.

3. The term "Validus" means plaintiff Validus Pharmaceuticals, Inc., and any parent, subsidiary, member and/or affiliated entity, past or present, of Validus, and any person or entity, past or present, acting on behalf of Validus, including, but not limited to, each of its present and former managers, officers, executives, directors, employees, attorneys, agents and/or representatives.

4. The term "action" means the lawsuit styled *Validus Pharmaceuticals, Inc., v. Actavis South Atlantic LLC, and Actavis, Inc.*, Civil Action No. 08-036, in the United States District Court, District of Delaware.

5. The term "patent-in-suit" means U.S. Patent No. 6,977,253 (the '253 patent).

6. The term "document" is used in this Discovery in the broadest sense as defined by Rule 34(a) of the Federal Rules of Civil Procedure, including all written, reported, recorded, electronic or graphic matter or things within the scope of Rule 26(b) of the Federal Rules of Civil Procedure, however produced or reproduced, including all drafts and all nonidentical copies (including those which are nonidentical by reason of notations or markings) of responsive documents, which is now or was at any time in the possession, custody or control of the party whom the document is requested or any other business entity (including corporations) under such party's control. Without limitation of the term "control" as used in the preceding sentence, the document or thing is deemed to be in the requested party's control if such party has the right to secure the document or a copy thereof from any person (including attorneys and accountants) or a public or private entity having actual possession thereof.

7. The term "communication(s)" refers to the exchange of information between any person or entity by or through any mode or medium including, but not limited to, the spoken word, written or electronic correspondence, face-to-face meetings and/or conveying information through third persons.

8. The terms "refer," "relate," or "relating" mean to refer to, pertain to, mention, discuss, represent, embody, illustrate, describe, reflect, support, negate, rebut, contradict, evidence, make reference to and/or constitute.

9. The connectors "and" and "or" shall be construed either disjunctively or conjunctively, as necessary, to bring within the scope of this request all responses that might otherwise be construed to be outside of the scope.

10. "Each" includes the word "every" and "every" includes the word "each." "Any" includes the word "all" and "all" includes the word "any."

11. The use of the singular form of any word includes the plural and vice versa.

12. The term "carbamazepine" has the same meaning in these requests as it does in the '253 patent.

13. The term "Equetro" shall be construed to include any designation of carbamazepine, including, but not limited to "Equetra," "Carbatrol" and SPD417.

14. The term "trial" shall include clinical and pre-clinical trials.

Instructions

1. This subpoena calls for you to produce all documents that are described below that are known or available to you, including all documents in the possession of or available to your present or former officers, directors, employees, agents, representatives, consultants, attorneys, subsidiaries, affiliates, principals or parents, or any investigators or any other person acting on your behalf or under your direction or control or under the direction or control of your attorneys or agents.

2. All documents that are responsive, in whole or in part, to any portion of this subpoena are to be produced in their entirety, without abbreviation or redaction, including all attachments or other materials affixed thereto. To the extent that responsive documents are maintained in both hard copy and magnetic media form, provide both forms.

3. All documents shall be produced both in the order and in the manner that they are kept in the ordinary course of business or they shall be organized and labeled to correspond with the categories of this subpoena. Whenever a document or group of documents is removed from a file folder, binder, file drawer, file box, notebook, or other cover or container, a copy of the label or other means of identification of such cover or other container shall be attached to the document.

4. If any document requested once existed, but has been lost, destroyed, or is no longer within your possession, custody, or control, identify all such documents and describe each document, its author(s), the recipient(s) or addressee(s), the subject matter, and content. Further, if any such documents have been destroyed, state with particularity the date and circumstances surrounding the reasons for destruction, and identify the last known custodian of each such document and each person or individual who has knowledge of the loss or destruction.

5. With respect to any documents otherwise responsive to this subpoena that, based on a claim of privilege or work product, you withhold or refuse to divulge, for each such document: (a) state the basis for your claim of privilege and the holder of the privilege; (b) state all facts relied upon in support of the privilege; (c) furnish a description of the document (i.e., title, subject matter, date, author and person(s) for whom it was prepared, to whom it was sent or

who otherwise received or saw the document or was aware of the substance of its contents); (d) identify all persons having knowledge of any facts relating to the claim of privilege; and (e) identify all events, transactions, or occurrences concerning the claim of privilege. If the claim of privilege applies to only a portion of the document, produce all portions of the document to which the claim does not apply.

6. All duplicates or copies of documents are to be provided to the extent they have any handwriting, additions (including highlighting and underlining), or deletions of any kind different from the original document being produced.

7. If a requested document is in a language other than English, produce both the original and any English translation(s) thereof.

8. If subsequent to the date on which you first produce documents responsive to this subpoena you discover or receive additional documents that are responsive to the requests herein, promptly produce all such additional documents to the full extent required by the Federal Rules of Civil Procedure and the Local Rules of this District Court.

Documents and Things to be Produced

1. All documents relating to U.S. Patent No. 6,977,253 (the '253 patent).

2. All documents and things relating to the prosecution of all patent applications in the same priority chain or family as the '253 patent, including U.S. Provisional Application No. 60/527,298, and U.S. Application No. 11/302,133.

3. All documents and things relating to the prosecution of all foreign or international patent applications related to the '253 patent, U.S. Provisional Application No. 60/527,298, and U.S. Application No. 11/302,133.

4. All documents and things relating to the prosecution of all U.S. and foreign patent applications related to carbamazepine products.

5. All documents and things relating to any and all patents included in the Orange Book listing for New Drug Application ("NDA") No. 21-710, including U.S. Patent Nos. 5,326,570 and 5,912,013.

6. All documents and things relating to the validity of the '253 patent.

7. All documents and things relating to the conception and reduction to practice of the subject matter claimed in the '253 patent.

8. All documents and things relating to the research, development, testing, manufacture, and/or production of the subject matter claimed in the '253 patent including research notebooks, lab notebooks, correspondence, invention disclosures, analysis, studies, experiments, reports, sketches, interview reports or summaries, any descriptions of tests, any data compiled during such tests, and any results or conclusions reached from such tests.

9. All documents relating to the title or ownership of the '253 patent.

10. All art known to Shire, regardless of the publication date, relating to the subject matter of the claimed invention of the '253 patent.

11. All references, publications, patents, and patent applications that were published, issued, or filed on or before May 19, 2004, that disclose, claim, describe, or teach drug delivery systems containing carbamazepine.

12. All documents and things relating to the treatment of bipolar disorder, mania or depression with carbamazepine or extended release carbamazepine.

13. All documents and things relating to the treatment of trigeminal neuralgia with carbamazepine or extended release carbamazepine.

14. All documents and things relating to any declarations or affidavits that relate to or discuss the subject matter claimed in the '253 patent.

15. All documents and things relating to the need for the inventions disclosed and claimed in the '253 patent.

16. All documents and things showing that the '253 patent is not obvious over prior art.

17. All documents and things relating to any review, discussion, or assertion that the '253 patent is sufficiently enabled.

18. All documents and things relating to any review, discussion, or assertion that the '253 patent meets the written description requirement.

19. All documents and things relating to any license, offer to license, agreement, or covenant relating to the subject matter recited in the '253 patent.

20. All documents and things relating to the decision to file NDA No. 21-710 rather than file a supplement to NDA No. 20-712 for Carbatrol.

21. All documents and things relating to communications with the FDA regarding the filing of NDA No. 21-710 rather than a supplemental NDA to Carbatrol.

22. All documents and things relating to communications with the FDA regarding references to Tegretol and Tegretol XR during the evaluation of NDA No. 21-710.

23. All documents and things relating to the decision to file NDA No. 21-710 as a 21 U.S.C. §505(b)2 application.

24. All documents and things relating to communications with the FDA regarding the filing of NDA No. 21-710 as a 21 U.S.C. §505(b)2 application.

25. All documents and things relating to any clinical studies or testing regarding carbamazepine, including, but not limited to, names and addresses of each person or entity performing the studies or testing, test protocols, data compilations, laboratory notebooks, summaries of results, drafts of reports, interim reports, final reports, published articles, financial remuneration, engagement of investigators, investigator agreements, internal memoranda and submissions of data to the FDA or any Foreign Government Regulatory Authorities.

26. All documents and things relating to any clinical studies or testing regarding the dosing regimen for carbamazepine, including all papers, abstracts, and drafts of the foregoing discussing the studies submitted to the FDA in support of the approval of NDA No. 21-710.

27. All documents and things relating to clinical study 105.302.

28. All documents and things relating to the 6-month continuation of open-label studies 105.301 and 105.302.

29. All documents and things relating to adverse events for all extended release carbamazepine products including but not limited to all documents, reports, or communications.

30. All documents and things relating to Quintiles Transnational Corp., its subsidiaries or affiliates, including any contracts, agreements, memoranda,

business plans, marketing plans, licenses, financial statements and any documents related to meetings, conversations, or negotiations between Shire and Quintiles Pacific, Inc.

31. All documents and things relating to the development and conduct of clinical trials performed at or by Quintiles Transnational Corp., its subsidiaries or affiliates relating to carbamazepine.

32. All clinical trial investigator protocols provided by Shire or any contractor firm to physicians, clinical investigators, or institutional review boards for clinical trials for carbamazepine and all contracts/agreements, including the names and addresses of each person or entity performing the studies or testing, with clinical trial investigators for these clinical trials.

33. All documents and things relating to any epidemiology studies regarding carbamazepine, including, but not limited to, names and addresses of each person or entity performing the studies or testing, test protocols, data compilations, summaries of results, drafts of reports, final reports, published articles, financial remuneration, engagement of investigators, internal memoranda and submissions of data to the FDA or any Foreign Government Regulatory Authorities.

34. Investigational New Drug ("IND") Application No. 59,050, including all documents and things submitted to or received from the FDA relating to IND No. 59,050.

35. All documents and things relating to any communications with the FDA or any Foreign Government Regulatory Authority regarding changes in the label or recommendations for use of Equetro.

36. All marketing literature, marketing plans, marketing devices, and all other marketing related documents and things for carbamazepine products offered for sale or sold anywhere in the world.

37. All documents and things relating to marketing and training materials for the launch of Shire's carbamazepine products.

38. All documents and things relating to physician or health care provider surveys, and feedback for Shire's carbamazepine products.

39. All documents and things relating to Validus, including, but not limited to any contracts, agreements, memoranda, business plans, marketing plans, licenses, financial statements and any documents related to meetings, conversations, or negotiations between Shire and Validus.

40. All documents and things relating to the transfer of NDA No. 21-710 from Shire to Validus, including without limitation documents and things relating to any purchase obligations, payment, royalty or other obligation arising from the transfer of NDA No. 21-710 from Shire to Validus.

41. All documents and things relating to the assignment of the '253 patent to Validus.

42. All documents and things relating to Actavis South Atlantic, LLC or Actavis, Inc.

43. All documents and things relating to any opinion on the validity or infringement of the '253 patent.

Deposition Topics

Pursuant to Rule 30(b)(6) of the Federal Rules of Civil Procedure, counsel for Actavis will take the videotaped deposition upon oral examination of Shire, on the subject matters set forth below.

1. The prosecution of the patents listed in the Orange Book for Equetro (U.S. Patent Nos. 5,326,570, 5,912,013, 6,977,253).

2. The development, manufacturing, FDA approval, and sales of Equetro.

3. All communications and documents relating to the transfer of NDA No. 21-710 from Shire to Validus, and all related communications and documents.

4. The documents requested by Actavis in this subpoena, including Quintiles's efforts to collect responsive documents.

CERTIFICATE OF SERVICE

I hereby certify that on September 3, 2008, a true and correct copy of the within document was caused to be served on the attorneys of record at the following addresses as indicated:

VIA ELECTRONIC MAIL

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Dawn Cook

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CERTIFICATE OF SERVICE

I, David E. Moore, hereby certify that on September 4, 2008, the attached document was electronically filed with the Clerk of the Court using CM/ECF which will send notification to the registered attorney(s) of record that the document has been filed and is available for viewing and downloading.

I further certify that on September 4, 2008, the attached document was Electronically Mailed to the following person(s):

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